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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/580,999

03/12/2007

Julia Y. Ljubimova

67789-586

9455

50670

7590

08/04/2009

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EXAMINER

PITRAK, JENNIFER S

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,999	Applicant(s) LJUBIMOVA ET AL.	
	Examiner JENNIFER PITRAK	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 18-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Remarks

Claims 1-13 and 18-23 are pending and are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 in that the provisional application, 60/527,300, does not provide support for a targeting molecule that promotes penetration of the blood brain barrier. Therefore, the instant claims are accorded the filing date of the instant application, which is 12/02/2004.

Applicant argues that support for penetration of the blood brain barrier exists in 60/527,300 because the '300 application recites a targeting antibody module against transferring receptor. This is not persuasive because the transferrin receptor is not exclusively expressed on endothelium cell surfaces that function as the blood brain barrier but are also expressed on many tumor cells as evidenced by Yu, et al. (2009, The AAPS J., v.11:195-230).

Deleted: Election/Restrictions¶

Applicant's election with traverse of Group I, claims 1-23, drawn to a drug delivery molecule, in the reply filed on 10/20/2008 is acknowledged. The traversal is on the ground(s) that the technical feature is not the cited polymerized carboxylic acid molecular scaffold, but rather that it is the combination of the polymerized carboxylic acid molecular scaffold with the plurality of biologically active molecular modules. This is not found persuasive because Applicant appears to be referring to the Office Action mailed 02/28/2008, rather than that mailed 08/18/2008. The special technical feature was identified as a polymerized carboxylic acid molecular scaffold complexed to biologically active molecular modules, which is known in the art as evidenced by Kabanov, et al. (U.S. Patent 7,056,532, of record) and by the art cited herein. ¶
The requirement is still deemed proper and is therefore made FINAL.¶
Applicant's election without traverse of a **targeting molecule that promotes penetration of the blood-brain barrier as a targeting molecular module** and of the **prodrug antisense molecule targeting alpha-4-laminin** in the reply filed on 10/20/2008 is acknowledged. ¶
Claims 1-28 are pending. Claims 24-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 14-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1-13 and 18-23 are under examination.

Claim Rejections - 35 USC § 112 - withdrawn

The rejection of claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

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applicant regards as the invention is withdrawn. The amendments to the claims have obviated the rejection.

Claim Rejections - 35 USC § 103 - Maintained

Claims 1-13 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass). This rejection is maintained for the reasons of record.

Response to arguments

Applicant argues that the LaFleur reference describes a drug delivery system and biologically active agents of the instant claims but that because they are not part of the same embodiment, they are not applicable to the present invention. This is not persuasive because the rejection is under 35 U.S.C. § 103 and relies not only of the teachings of LaFleur, but also of additional references as indicated in the rejection of record.

Applicant also argues that the antisense oligonucleotides taught by LaFleur, et al. are not taught as drug delivery compounds. This is not persuasive because LaFleur teaches the in vivo use of antisense oligonucleotides in the cited portions of the reference.

Applicant argues that the scaffold described by LaFleur is not covalently linked to the active modules and therefore cannot be compared to the instant invention. This is not persuasive because, as indicated in the rejection, Cammas, et al. is relied upon to teach covalent linkage.

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Applicant argues that claims 3-5 are further distinguished from the LaFleur reference because the claims are limited to poly(β -L-malic acid). This is not persuasive because LaFleur does not exclude poly(β -L-malic acid).

Applicant argues that LaFleur describes the use of antibodies as analytical agents, not for promoting cellular uptake. This is not persuasive because the cited portion of the reference indeed teaches the use of antibodies for cell targeting and in vivo therapy.

Applicant argues that the Cammas reference is unlike the present invention in that the reference does not teach covalent attachment of drugs to carriers, the reference discusses a very different type of chemistry than that which is described in the instant application. This is not persuasive because Cammas teaches that the introduction of biologically active molecules or targeting moieties can be accomplished by appropriate chemical modifications.

Claims 1-13 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass) as applied to claims 1-13 and 20 above, and further in view of Saito, et al. (2003, Adv. Drug Del. Rev., v.55:199-215, item 63 on 11/08/2007 IDS) (Saito). This rejection is maintained for the reasons of record.

Response to arguments

Applicant's arguments regarding this rejection have been addressed in the preceding rejection.

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Claims 1-13, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass) as applied to claims 1-13 and 20 above, further in view of Summerton, et al. (1997, Nuc. Acid Drug Dev., v.7:187-95, item 38 on 11/08/2007 IDS) (Summerton). This rejection is maintained for the reasons of record.

Response to arguments

Applicant's arguments regarding this rejection have been addressed in the preceding rejection.

Claims 1-13, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass) as applied to claims 1-13 and 20 above, further in view of Khazenzon, et al. (2003, Mol. Cancer Ther., v.2:985-94, item 47 on 11/08/2007 IDS) (Khazenzon). This rejection is maintained for the reasons of record.

Response to arguments

Applicant's arguments regarding this rejection have been addressed in the preceding rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak
Examiner
Art Unit 1635

/Sean R McGarry/
Primary Examiner, Art Unit 1635